

REMARKS

I. Status of the Application

Claims 1-48 are presently pending and stand rejected. By way of this response, claims 1, 25, 27, and 47 have been amended and new claims 49-51 have been presented. Applicant respectfully submits that no new matter has been added by way of this amendment.

II. Rejection Under 35 U.S.C 102(e)

In the Office Action dated March 18, 2008, the Examiner made a rejection of claims 1-13, 15-34, and 36-48 under 35 U.S.C. § 102(e) as being anticipated by Van der Hoop (U.S. PG Publication 2003/0027804). Under 35 U.S.C. § 102(e), in order for a prior art reference to anticipate a claim, the reference must teach each and every element of the claim. *See, e.g.,* M.P.E.P. § 2131.02 ("The identical invention must be shown in as complete detail as is contained in the ... claim"); *see also Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, Applicant respectfully traverses the rejection and respectfully requests that the rejection be withdrawn in light of the arguments set forth below and the present amendments to claims 1, 25, 27 and 47.

Van der Hoop does not anticipate the use of phosphodiesterase inhibitors in combination with testosterone for the administration of a gel formulation to treat erectile dysfunction. More specifically, Van der Hoop at paragraph [0068] states that "[w]here the invention is illustrated herein with particular reference to methyltestosterone, it will be understood that any other inhibitor of the synthesis of sex hormone binding globulin can, if desired, be substituted in whole or in part for methyltestosterone in the methods, combinations and compositions herein described." Therefore, the purpose of Van der Hoop is to teach a method to increase sex steroid levels through the use of sex binding globulin synthesis inhibiting agents such as methyltestosterone. Phosphodiesterase inhibitors do not inhibit the synthesis of sex hormone binding globulin and thus were not anticipated by Van der Hoop. From a mechanistic standpoint, phosphodiesterase inhibitors regulate sex steroid levels differently than methyltestosterone. Specifically, phosphodiesterase inhibitors increase the levels of cyclic GMP, which in turn leads to an increase in sex steroid levels. The focus of Van der Hoop is on the use

of methyltestosterone instead of phosphodiesterase inhibitors, and subsequently, does not teach every claim of the current amended application.

Claim 1 of the current application, as amended, excludes all of the known compounds that inhibit synthesis of sex hormone binding globulin that include, but are not limited to, methyltestosterone and fluoxymesterone, and all salts, esters, amides, enantiomers, isomers, tautomers, prodrugs and derivatives of these compounds. Claim 27 of the current application, as amended, recites that phosphodiesterase inhibitors will be the sole additional pharmaceutical that will be administered to the subject after administration of the gel formulation. Therefore, Applicant respectfully traverses the rejection and respectfully requests that the rejection be withdrawn.

III. Rejection Under 35 U.S.C. 103(a)

In the Office Action of March 18, 2008, the Examiner also rejected claims 14 and 35 under 35 U.S.C. § 103(a) as being unpatentable over Van der Hoop as applied to claims 1-13, 15-34, and 36-48 above and further in view of Hussain (U.S. Patent No. 6,200,591). Applicant respectfully traverses the rejection and respectfully requests that the rejection be withdrawn in light of the arguments set forth below and the present amendments to the claims.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the references when combined must teach or suggest all the claim limitations. See M.P.E.P. § 2143.

The burden of establishing a *prima facie* case of obviousness lies with the PTO. In determining obviousness, one must focus on the invention as a whole. *Symbol Technologies Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1577-78, 19 U.S.P.Q. 2d 1241 (Fed. Cir. 1991). The primary inquiry is: “[w]hether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have had a reasonable likelihood of success ... Both the suggestion and the expectation of success must be found in the prior art, not the

applicant's disclosure." *In re Dow Chemical*, 837 F.2d 469, 473, 5 U.S.P.Q. 2d 1531 (Fed. Cir. 1988).

As will be discussed in detail below, Applicant submits that no *prima facie* case of obviousness has been established because the references do not disclose each and every element of the claimed invention, and because no motivation to combine these references exists.

A. The references when combined do not teach or suggest all claim limitations

In light of the fact that Van der Hoop does not anticipate the use of phosphodiesterase inhibitors under 35 U.S.C. § 102(e), claims 14 and 35 are not unpatentable over Van der Hoop as applied to claims 1-13, 15-34 and 36-48 above, and further in view of Hussain. Again, to establish a *prima facie* case of obviousness, all the claim limitations must be taught or suggested by the prior art. *See, e.g.*, M.P.E.P. § 2143.03 ("All words in a claim must be considered in judging the patentability of that claim against the prior art"); *see also In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494 (C.C.P.A. 1970)). In this case, none of the references cited by the Examiner teach or suggest all of the claim limitations. Particularly, Van der Hoop and Hussain do not, alone or in combination, suggest a method for administering the combination of testosterone gel formulations and phosphodiesterase inhibitor as a treatment for male erectile dysfunction.

CONCLUSION

For at least the foregoing reasons, it is respectfully submitted that amended claims 1, 25, 27 and 47 and new claims 49-51 and dependent claims 2-26 and 28-48 are in condition for allowance. Early and favorable consideration is respectfully requested, and the Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution.

Further, none of Applicant's amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicant reserves all rights to pursue any such subject matter in this or a related patent application.

Respectfully submitted,

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